



Health Technology Certification

# EC-CERTIFICATE

## FULL QUALITY ASSURANCE SYSTEM

This is to certify that the quality management system of

### SHAH EYE CARE PRIVATE LIMITED

Plot No : 8 & 9, Karur Industrial Area, P. B. Road, Davangere,  
Karnataka, India-577006

for design and manufacture of

### Ophthalmic Microsurgical Knives

See attachment for Certificate history

fulfills the requirements of Annex II excluding (4) of Council Directive 93/42/EEC.

The use of CE Marking followed by the HTCert Notified Body identification number 2803 for the devices listed on the certificate is hereby authorised. The certificate remains valid subject to satisfactory surveillance audits, periodic or unexpected. Any significant changes in design or manufacture may render this certificate invalid. For class III devices covered by this certificate an EC Design Examination Certificate according to Annex II, Section 4 is required. For class I sterile devices the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.

Certificate No: 1724C04210402  
Issue Date: 24/04/2021  
Original Approval: 18/08/2020  
Valid until: 26/05/2024  
References: W001 1724 02

HTCert is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification number 2803

For and on behalf of HTCert

GEORGE PAPPOUS  
Managing Director

FILIPPOS KOTTIS  
Certification Director

  
  
p 1/2



Health Technology Certification



## Attachment to Certificate

No: 1724C04210402

Issued: 24/04/2021

### Certificate History

Issue date	Certificate Number	Reason for Issuance
18/08/2020	1724C04200801	First issuance
24/04/2021	1724C04210402	Change of company address

For and on behalf of HTCert

**GEORGE PAPPOUS**  
Managing Director

**FILIPPOS KOTTIS**  
Certification Director



p 2/2

# CERTIFICATE OF REGISTRATION



*This is to Certify that the  
Medical Devices – Quality Management System  
of*

## **SHAH EYE CARE PRIVATE LIMITED**

**PLOT 8 TO 9, KARUR INDUSTRIAL AREA, P B ROAD,  
DAVANGERE -577006, KARNATAKA, INDIA**

**has been independently assessed and is compliant  
with the requirements of**

### **ISO 13485:2016**

**This Certificate is applicable to the following product or service ranges:**

**DESIGN, MANUFACTURE & DISTRIBUTION OF OPHTHALMIC MICRO SURGICAL  
KNIVES, TROCAR SETS, OPHTHALMIC INSTRUMENTS, CANNULAS,  
CUSTOMS SURGICAL PACK, DRAPES, SURGICAL GOWNS,  
TABLE / TROLLEY CLOTH, 3PLY MASK.**

*:: Certificate No :: IN53417H*

<b>Date of initial registration</b>	<b>30 October 2020</b>
<b>Date of this Certificate</b>	<b>30 October 2020</b>
<b>Surveillance audit on or before</b>	<b>29 October 2021</b>
<b>Recertification Due / Certificate expiry</b>	<b>29 October 2023</b>

This Certificate is remains valid subject to satisfactory surveillance audits.

**Emmanuel ADEMOSU**  
**Director**



For verification and updated information concerning the present certificate visit to [http://staunchlyservices.com/search\\_certified\\_client.php](http://staunchlyservices.com/search_certified_client.php)  
This Certificate is the property of Staunchly Management & System Services Limited and shall be returned immediately when demanded

#### **STAUNCHLY MANAGEMENT AND SYSTEM SERVICES LIMITED**

Labrynth Business Centre, 43 Middle Hill Gate, Stockport,

Great Manchester, England-SK1 3DG

Web :- [www.staunchlyservices.com](http://www.staunchlyservices.com)

E-mail :- [info@staunchlyservices.com](mailto:info@staunchlyservices.com)

Phone :- +44 740 482 3687

Company Registered in England and Wales with Company Number 11488683





# Certificate of Registration 2021

*This is to certify that the registration of*

**SHAH EYE CARE PRIVATE LIMITED**

PLOT NO: 8 & 9, KARUR INDUSTRIAL AREA, P.B. ROAD, DAVANGERE  
KARNATAKA, INDIA - 577006

*with U.S. Food and Drug Administration as required by 21 CFR Part 807 is successfully completed by Liberty Management Group Ltd. with the information provided by the above company.*

**FEI Number** : 3013530125  
**Date of Expiration** : December 31, 2021  
**U.S. Agent** : LIBERTY MANAGEMENT GROUP LTD.  
**Certificate Number** : 3012260120

*This certificate does not make representations or warranties to any person or entity other than the named certificate holder; it is issued for record keeping purpose only. This certificate does not denote endorsement or approval of certificate holder's facility or product by the U.S. food and Drug Administration. Liberty management Group Ltd. assumes no liability to any person or entity in connection with the foregoing.*

*The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Liberty Management Group Ltd. is not affiliated with the U.S. Food and Drug Administration.*

**LMG** LIBERTY  
MANAGEMENT  
GROUP LTD.

75 Executive Drive, Aurora, Illinois, USA  
[www.fdahelp.us](http://www.fdahelp.us)

A handwritten signature in black ink, reading "Manoj Zacharias".

Manoj Zacharias

President

Liberty Management Group LTD.

Dated: December 26, 2020